

AMENDMENTS

IN THE CLAIMS

Please amend the claims as follows:

a' Claim 18: [amended] The method according to claim 16, wherein said target comprises a protein that binds to said carrier.

REMARKS

The Amendment

Applicant has amended claim 18 to correct an obvious typographical error. Specifically, claim 18 depended from itself as originally filed. Applicant has amended claim 18 to depend from claim 16. This is supported in the specification at page 11, lines 18-30.

The Restriction Requirement

The Examiner states that restriction of the application into one of the following four inventions is required under 35 U.S.C. § 121:

- I. Claims 1-15, drawn to a complex comprising a target binding/cavity forming moiety, a cavity forming moiety, and a pharmacological compound.
- II. Claim 16-22, drawn to a method of delivering a pharmacological compound to a target in a patient.
- III. Claims 23, drawn to a method of purifying pharmacological compounds away from unwanted chiral forms.
- IV. Claims 24-26 [*sic*], drawn to a method for producing a complex.

Applicant traverses.

Examiner's Office Action Summary states that claims 1-28 are pending in the application, however claims 27 and 28 have not been assigned to a restriction group. Applicant assumes that claims 27 and 28, which depend from claim 24, would fall within Group IV, as the Examiner has restricted the claims.

Originally filed claims 1-15 have issued in United States patent 6,406,710 (the "710 patent"). Therefore, claims 16-28 are under consideration in the instant application.

The Instant Restriction

The Manual of Patent Examining Procedure (MPEP) states that there are two criteria for a proper requirement of restriction between patentably distinct inventions. The first is that the inventions must be independent or distinct as claimed. The second is that there must be a serious burden on the Examiner if restriction is not required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" MPEP § 803 (emphasis added).

The claims of Groups II-IV of the instant application are directed to methods of delivering a pharmacological compound, purifying a pharmacological compound or producing a complex for delivering a pharmacological compound. The claims of Groups II, III and IV of the instant application should not be separated from each other because the claims of each Group include as a common point of novelty the complex of now-issued claim 15. A search for methods employing the complex of now-issued claim 15 in delivering or purifying a compound would necessarily be co-extensive with each other, as well as coextensive with a search for the methods for producing a

complex for delivering a pharmacological compound, and would therefore not impose a serious burden on the Examiner.

Examiner states that "Group II requires the search and consideration of efficacy of therapy by administration of a target binding moiety/cavity forming moiety/pharmacological compound complex to a patient, which is not required by the other inventions. Applicant respectfully disagrees. Efficacy of therapy is not required by the claims of Group II, only administration. As in the claims of Groups III and IV, there is the use of the complex of now-issued claim 15. Additional claim steps would not constitute an undue search burden where the complex employed in the method is known to be novel.

The Examiner's discussion at 1.b. and 1.c. regarding differences between Group I and Groups II/IV and III is moot, as the claims of Group I have issued.

The Examiner further states that the applicant is required, under 35 U.S.C. 121, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In section 3., the Examiner cites the list of targets found in claims 17 and 18 as species that must be elected. In section 4., the Examiner cites the targets of claims 19 and 21 as species that must be elected. In section 5., the Examiner cites the targets of claim 22 as species that must be elected. In each of these cases, applicant believes that a species election should not be required.

The Manual of Patent Examining Procedure (MPEP) states that if the members of Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the

examiner must examine all members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. MPEP 803.02

In the instant case, applicant asserts that for each of claims 17-19 and 21-22, the claimed targets are closely related in the context of the claim such that there can be no serious search burden. For example, the targets listed in claim 17 are destination sites in the body for pharmacological therapy. Similarly, the targets listed in claims 18, 19, 21 and 22 are proteins that are candidates for drug targeting in the body.

Thus, a search for members of the groups of claims 17-19 and 21-22 would necessarily be co-extensive with a search for other members of the respective Markush groups and would therefore not impose a serious burden on the Examiner. For example, a search for a method delivering a pharmacological compound to a target in a patient wherein the target is a “cell,” “tissue” or “organ” would be co-extensive with each other and would not impose a serious burden on the Examiner.

Furthermore, the MPEP states that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. The MPEP further states that unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. MPEP 803.02.

The targets for the complexes of this invention recited in claims 17-19 and 21-22 share a common utility and a substantial structural feature essential to that utility: they are each surfaces capable of binding the target-binding moiety of the complexes of applicant's inventions.

Restriction In The Parent Application

In the prosecution of the parent application, one of the Examiners in that case restricted the 28 originally-filed claims into three restriction groups*:

- I. Claims 1-15
- II. Claims 16-22
- III. Claims 23-28

These are the same claims identified by the Examiner in the instant Office Action. Applicant relied on the restriction in the parent application in choosing to prosecute the claims that issued in the '710 patent. Should the Examiner maintain her restriction of the pending claims into Groups II, III, and IV, applicant submits that, based on the restriction in the parent application, at least claims 23-28 may properly be examined together without undue burden to the Examiner.

Conclusion

1) Species Restriction

Based on the above remarks, applicant requests that the Examiner withdraw the requirement under 35 U.S.C. 121 to elect single disclosed species for prosecution on the merits. However, if the Examiner maintains her species restrictions, pursuant to 37 C.F.R. § 1.143, applicant provisionally elects, with traverse, the following species for further prosecution in this application:

A method of delivering a pharmacological compound to a target in a patient, wherein the target is a cell.

* Applicant has attached at Tab A a copy of a November 8, 1999 Office Action in parent application 09/101,860.

A method of delivering a pharmacological compound to a target in a patient, wherein the target is a protein and the protein is a cell surface protein.

A method of delivering a pharmacological compound to a target in a patient, wherein the target is a protein and the protein is trkA.

This provisional election is made expressly without waiver of applicant's rights to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or in other applications claiming benefit herefrom.

2) Claim Restriction

Applicant believes that Groups II, III and IV should be considered together because there is no undue search burden for the Examiner to examine the subject matter of these groups in a single application. If the Examiner does not agree with this proposal, pursuant to 37 C.F.R. § 1.143, applicants elect, with traverse, the claims of Group II, containing claims 16-22 directed to methods of delivering a pharmacological compound to a target in a patient, for initial substantive examination. This provisional election is made expressly without waiver of applicant's rights to continue to prosecute and to obtain claims to the non-elected subject matter either in this application or in other applications claiming benefit herefrom.

Based on the above remarks, applicant requests that the Examiner withdraw her restriction of claims 16-22, 23 and 24-26 into three groups; withdraw the requirement to elect single disclosed species; and allow claims 16-28 to issue.

Respectfully submitted,



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Amended Claim

Claim 18: [amended] The method according to claim 16, wherein said target comprises a protein that binds to said carrier.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,860 07/16/98 PANAYOTATOS

N NP/101P

EXAMINER

HM12/1108

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BENSTON JR., W

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

11/08/99

Please find below and/or attached an Office communication concerning this application proceeding.

Commissioner of Patents and Trad marks

DOCKETED FOR

2/8/00

RECEIVED

NOV 12 1999

FISH & NEAVE - PATENT DEPT.
REFERRED TO CR
NOTED BY

Office Action Summary

Application No.

071101,860

Applicant(s)

KANAYOTATOS

Examiner

Rensston

Group Art Unit

1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2-5-99
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-28 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-28 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1615

15) Receipt of IDS dated 2-5-99 is acknowledged.

16) Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17) The phrases "a complex" and "moiety" in claims 1-28 are relative terms which render the claim indefinite. The phrase "moiety" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "a complex" is vague and indefinite as said phrase can be defined in such a broad way as to make it very hard to make sense when used with other terms such as "moiety," and/or "target." All of these terms are too broad for describing said inventive concept(s). For example, could the word "matrix" be used in place of "complex?" A correction of said phrases is requested.

18) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15 are, drawn to pharmaceutical composition/complex, classified in class 424, subclass 400.

II. Claims 16-22 are, drawn to method of delivering, classified in class 530, subclass 350+.

19) III. Claims 23-28, drawn to method of producing/purifying, classified in class 435, subclass 68.1+.

20) The inventions are distinct, each from the other because:

Art Unit: 1615

21) Inventions II, III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as for example to take advantage of the known specificity of receptor/peptide ligand interactions and make ligand/toxin fusions that selectively destroy cells displaying the cognate receptor..

22) Any inquiry concerning this communication or earlier communications from the examiner should be directed to William E. Benston, Jr., whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday-Friday from 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

 W. Benston; CV

10/5/99

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